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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/460,292 12/10/99 MANGELSDORF

D UTSD: 596

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HM22/0913

EXAMINER

WOITACH, J

ART UNIT	PAPER NUMBER
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1632

DATE MAILED:

09/13/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

File

Office Action Summary

Application No.

09/460,292

Applicant(s)

Mangelsdorf, D. et al.

Examiner

Joseph Weitach

Group Art Unit

1632

☐ Responsive to communication(s) filed on _____☐ This action is **FINAL**.☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims☒ Claim(s) 1-58 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.☐ Claim(s) _____ is/are rejected.☐ Claim(s) _____ is/are objected to.☒ Claims 1-58 are subject to restriction or election requirement.**Application Papers**☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on _____ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.☐ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119**☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been☐ received.☐ received in Application No. (Series Code/Serial Number) _____.☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)**☐ Notice of References Cited, PTO-892☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____☐ Interview Summary, PTO-413☐ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

This application is an original application filed December 10, 1999, which claims to the provisional application 60/111,894, filed December 10, 1998. Claims 1-58 are pending and under current examination.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-14, 21-29, 44 and 45, drawn to transgenic non-human mammal wherein the cells contain at least one non-functional LXR α allele, cells containing said non-functional allele and a method to use said animal for screening substances that increase bile acid synthesis, classified in class 800, subclasses 14 and 3; class 435, subclass 325.
- II. Claims 15-20, drawn to method to screen RXR or LXR α agonists which increase bile acid synthesis, classified in class 435, subclasses 4, 375.
- III. Claims 30-43, 46 and 47, drawn to method to screen for a rexinoid which reduce cholesterol levels in an intestinal cell the method to use cells classified in class 435, subclasses 4, 375.
- IV. Claims 34-43, drawn to method for reducing cholesterol levels in a mammal with a RXR agonist classified in class 435, subclasses 4, 375, class 514, subclass 1.

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- V. Claims 48-58, drawn to a method for screening for a modulator of ABC1 expression, classified in class 435, subclasses 4, 325.

The inventions are distinct, each from the other because of the following reasons:

Groups I-V are drawn to products and methods which are different and distinct, and capable of separate use. For example, while groups I and II both are methods screen for substances which increase bile synthesis the method practiced in group I is done *in vivo* and encompasses any mechanism which would increase bile acid synthesis, and the method of group II is done *in vitro* specifically looking for an agonist of RXR or LXR. The inventions of groups III and IV are drawn to methods which affect cholesterol levels, however group III is drawn specifically to the ability of a rexinoid on an intestinal cell while group IV is drawn to methods done *in vivo* and looks at the effect of RXR agonists on any cell type. Group V is a method drawn to examining modulators of ABC1 expression which does not necessarily have an effect on bile acid or cholesterol levels and so is unrelated to groups I-IV.

The materials and method steps needed to the practice the method of each of the inventions are different and unique. The inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above invention is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of any one Group would not necessarily anticipate or make obvious any of the other groups.

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For these reasons restriction for examination is proper.

A telephone call was made to Steven L. Highlander on September 6, 2000 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach, whose telephone number is (703) 305-3732. The examiner can normally be reached on Monday through Friday from 8:00 to 4:30 (Eastern time).

If attempts to reach the examine by telephone are unsuccessful, the examiner's supervisor, Karen M. Hauda, can be reached on (703) 305-6608. The fax number for group 1600 is 1 (800)308-4242.

An inquiry of a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is (703) 308-0196.

Joseph T. Woitach


Patent Examiner
AU 1632